ISO/TC 84/WG 3 ad hoc 5

N12

Needle-free injectors for medical use

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Meeting notes on afternoon session 21 October 1999

by Linda D'Antonio

ISO/TC 84/WG3/ad hoc group 5 "Needle-free injectors for medical use"

Meeting Notes 21 October 1999 (afternoon session)
Prepared by: Linda D'Antonio

The discussion group included Antonio Bendek (B-D), Linda D'Antonio (DCI), Richard Hall (PowderJect), Peggy Holland (Medi-Ject), Sam Nickerson (Bioject), Mike Roy (PowderJect).

Our aim was to begin developing requirements for needle-free injectors as defined in the scope developed in previous meetings of the working group. We worked from the list of General Requirements defined at the 28 July 1999 meeting as well as from the pen-injector standard (ISO/FDIS 11608-1:(E) Pen-injectors for medical use – Part 1: Pen injectors – Requirements and test methods).

The group agreed on the following list of General Requirements:

4.1 General Requirements

When the needle-free injector is ready for injection, there is an indication to the user that deliverable medicinal product is present. It shall be possible to determine whether sufficient medicinal product remains to administer the intended dose.

The needle-free injector shall be designed such that it is able to deliver the labelled quantity from the medicinal container for which it is designed.

The needle-free injector shall indicate the pre-set dose.

The needle-free injector shall indicate, at least by visual means, that the device is ready for injection.

The needle-free injector shall indicate, by visual or auditory or tactile means, that the injector has been actuated.

The state of the needle-free injector, when ready to deliver a dose, shall be different to its state when the dose has been delivered. The difference shall be visible.

For variable-dose needle-free injectors, the device shall be designed so it is impossible to deliver a second dose after delivery of the first dose without a second pre-setting operation.

Following the discussion of General Requirements, we moved on to section 4.2.2 Freedom from defects, which led us to sections 5.5 Visual inspection and 5.6 Functional inspection. The group agreed that section 5.5 Visual inspection was acceptable as written in the pen-injector standard (with the appropriate changes from pen-injector to needle-free injector).

In our discussion of section 5.6 Functional inspection, we began to debate the various classes of injectors that must be tested. As a result of this debate, we chose to move into section 3

Definitions and nomenclature. We developed a preliminary list of necessary definitions, although we did not have time to complete the definitions.

3 Definitions and nomenclature

3.1 needle-free injector
[take definition from scope]
3.1.1 reusable
3.1.2 disposable

3.2 medicinal container
3.2.1 reusable
3.2.2 single-use disposable
3.2.3 multi-use disposable